

# LIVE, INTRANASAL INFLUENZA VACCINE

## WHAT YOU NEED TO KNOW

# 2003-2004

### 1 Why get vaccinated?

**Influenza (“flu”) is a serious disease.**

It is caused by a virus that spreads from infected persons to the nose or throat of others.

Influenza can cause:

- fever
- sore throat
- chills
- cough
- headache
- muscle aches

Anyone can get influenza. Most people are ill with influenza for only a few days, but some get much sicker and may need to be hospitalized. Influenza causes an average of 36,000 deaths each year in the U.S., mostly among the elderly.

**Influenza vaccine can prevent influenza.**

### 2 Live, intranasal influenza vaccine

Two types of influenza vaccine are now available. Live, intranasal influenza vaccine (trade-name FluMist™) was licensed in 2003. FluMist is an attenuated (weakened) live vaccine. It is sprayed into the nostrils rather than injected into the muscle.

Inactivated (killed) influenza vaccine, sometimes called the “flu shot,” has been used for many years, and is given by injection.

### 3 Who can get live, intranasal influenza vaccine?

Live, intranasal influenza vaccine is approved for healthy children and adults from 5 through 49 years of age, including household contacts of some people at high risk for influenza complications. However, because its safety has not yet been studied in some other groups, FluMist should not be used by many people at risk for flu or its complications (see Section 4).

### 4 Who should *not* get live, intranasal influenza vaccine?

The following people should not get intranasal influenza vaccine. They should check with their health care provider about getting **inactivated influenza vaccine**.

- **Adults 50 years of age or older or children younger than 5.**
- People who have **long-term health problems** with:
  - heart disease
  - kidney disease
  - lung disease
  - metabolic disease, such as diabetes
  - asthma
  - anemia, and other blood disorders
- People with a **weakened immune system** due to:
  - HIV/AIDS or another disease that affects the immune system
  - long-term treatment with drugs that weaken the immune system, such as steroids
  - cancer treatment with x-rays or drugs
- Children or adolescents on **long-term aspirin treatment** (these people could develop Reye syndrome if they catch influenza).
- **Pregnant women.**
- Anyone with a history of **Guillain-Barré Syndrome (GBS)**.

The flu shot (inactivated vaccine) is preferred over live, intranasal influenza vaccine for physicians, nurses, family members, or anyone else coming in **close contact with anyone with a weakened immune system**.

The following people should talk with a doctor before getting *either* flu vaccine:

- Anyone who has ever had a serious allergic reaction to **eggs** or to a **previous dose** of influenza vaccine.
- If you have a fever or are severely ill at the time the vaccination is scheduled, you should probably wait until you recover before getting influenza vaccine. Talk to your doctor or nurse about whether to reschedule the vaccination.

## 5 When should I get influenza vaccine?

The best time to get flu vaccine is in **October** or **November**. But live, intranasal flu vaccine may be given as soon as the vaccine is available. The flu season usually peaks anywhere from January through March, so getting the vaccine in December, or even later, can be beneficial in most years.

Most people need only one flu vaccination each year to prevent influenza. But children through 8 years of age getting influenza vaccine *for the first time* should get 2 doses of vaccine. For the live, intranasal vaccine, these doses should be 6-10 weeks apart. These children should get their first dose in October or earlier.

Live, intranasal flu vaccine may be given at the same time as other vaccines. This includes other live vaccines, such as MMR or chickenpox. But if two live vaccines are not given on the same day, they should be given at least 4 weeks apart.

Influenza viruses change often. Therefore, influenza vaccines are updated every year, and an annual vaccination is needed.

## 6 What are the risks from live, intranasal influenza vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live, intranasal influenza vaccine can cause mild symptoms (see below).

### Mild problems:

Some children and adolescents 5-17 years of age reported mild reactions during clinical studies, including:

- runny nose or nasal congestion
- fever
- headache and muscle aches
- abdominal pain or occasional vomiting

These problems usually happened after the first dose and went away on their own.

Some adults 18-49 years of age reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

During clinical studies with live, intranasal influenza vaccine, many of these symptoms occurred whether or not the person was vaccinated. Even when they occurred after vaccination, they may not have been caused by the vaccine.

### Severe problems:

- Life-threatening allergic reactions are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.
- No life-threatening reactions were reported during clinical trials of live, intranasal influenza vaccine. However, rare reactions may not be identified until thousands or millions of people have used any new product. Monitoring for unusual or severe problems is being done.

## 7 What if there is a moderate or severe reaction?

### What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

### What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing an Vaccine Adverse Event Reporting System (VAERS) form. Or call VAERS yourself at **1-800-822-7967**, or visit their website at **www.vaers.org**.

## 8 How can I learn more?

- Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-2522** (English)
  - Call **1-800-232-0233** (Español)
  - Visit CDC websites at **www.cdc.gov/ncidod/diseases/flu/fluvirus.htm** or **www.cdc.gov/nip**



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